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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
EPPERSON, JON D	
ART UNIT	**PAPER NUMBER**
1639	

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10/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/693,802	EGGEN ET AL.	
	Examiner	Art Unit	
	Jon D. Epperson	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-46 and 48-63* is/are pending in the application.

4a) Of the above claim(s) *40,43,50-54 and 58-62* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-39,41,42,44-46,48,49,55-57 and 63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/29/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

1. The Response filed July 26, 2007 is acknowledged.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior office action.

Status of the Claims

3. Claims 28-46 and 48-55 were pending. Applicants added claims 56-63. No claims were amended or canceled. Therefore, claims 18-46 and 48-63 are currently pending. Claims 40, 43, 50-54, 58-62 are drawn to non-elected species and/or inventions and thus these claims remain withdrawn from further consideration by the examiner, 37 CFR 1.142(b), there being no allowable generic claim. Therefore, claims 28-39, 41, 42, 44-46, 48, 49, 55-57 and 63 are examined in this action.

Withdrawn Objections/Rejections

4. All rejections are maintained and the arguments are addressed below.

Outstanding Objections and/or Rejections

Claim Rejections - 35 USC § 102

5. Claims 28, 30, 31, 36, 41, 42, 44-46, 49 and 55 are rejected under 35 U.S.C. 102(b) as being anticipated by Carpino et al. (Carpino, et al. "The 1,1-Doxobenzo[b]thiophene-2-

ylmethyloxycarbonyl (Bsmoc) Amino-Protecting Group J. Org. Chem. 1999, 64, 4324-4338) (10/23/03 IDS Reference AR) as evidenced by Solomons (Solomons, T. W. G. Organic Chemistry Fifth Edition. New York: John Wiley and Sons. 1992, page 94, Table 3.1) and Lide (CRC Handbook of Chemistry and Physics, ed. DA Lide, 85th edn., CRC Press, Cleveland, OH, **2004-2005**, web page 1) and STN (STN Express, Registry No. 141-43-5, chemical properties listing, page 1).

For ***claims 28***, Carpino et al. disclose processes for the rapid solid phase and/or solution phase peptide synthesis using Bsmoc amino protecting groups in conjunction with various scavenging agents (e.g., see abstract), which anticipates claim 28. For example, Carpino et al. disclose **(a)** a coupling step, using an excess of an activated carboxylic acid component to acylate an amino component (e.g., see Carpino et al., page 4329, scheme 1 wherein H-AA_1-OR is coupled to an excess of Bsmoc-AA_2-OH to form Bsmoc-AA_2-AA_1-OR using HATU and DIEA, the excess Bsmoc-AA_2-OH is removed by the $NH_2(CH_2CH_2)_3N$; see also page 4327, middle paragraph, "A second byproduct, derived from excess acylating agent, is the amide 16"). Carpino et al. further disclose **(b)** a quenching step in which a scavenger is used to remove residual activated carboxylic acid and also using said scavenger to deprotect the growing peptide (e.g., see page 4329, scheme 1 wherein the Bsmoc protecting group and the excess AA_2 are removed; see also page 4327, compounds 15 and 16). Carpino et al. disclose **(c)** the use of one or more aqueous extractions (e.g., see page 4329, scheme 1 showing removal of water soluble side products; see also page 4327, middle paragraph; see also abstract, "Application [of Bsmoc amino-protecting groups] ... represents a significant improvement over the

corresponding Fmoc-based method for rapid solution synthesis due to the opportunity to use water or saturated sodium chloride solution rather than an acidic phosphate buffer to remove [i.e., extract] all byproducts"). Carpino et al. also disclose at least one step (b), referred to as step **(b')**, in which an amine comprising a free anion or a latent anion is used as a scavenger of residual activated carboxylic acid (e.g., see page 4329, column 1, first paragraph wherein "ethanolamine" is disclosed). The reference does not state that ethanolamine possesses a "free anion or latent anion", but the Examiner contends that this would be an inherent property of ethanolamine via the following equilibrium in water $NH_2CH_2CH_2OH \rightleftharpoons NH_2CH_2CH_2O^- + H^+$) (e.g., see Lide, web page 1, "Dissociation Constants of Organic Acids and Bases" section, Ethanolamine entry wherein pK_a = 12.87; see also Solomons, page 94, Table 1, wherein pK_a of water = 15.74; see also STN Express registry data showing pKa = 12.87 showing that alcohol is more acidic than water, probably due to stabilization by amine). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). The Office does not have the facilities to make such a comparison and the burden is on the applicants to establish the difference. See *In re Best,* 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray*, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.)." Finally, Carpino et al. also disclose repeating steps (a)-(c) above to synthesize a full-length peptide and/or protein (e.g., see page 4329, wherein "additional cycles" are disclosed; see also experimental section wherein longer peptides are produced).

For ***claim 30***, Carpino et al. disclose pre-activation of carboxylic acid, for example, via cyanuric fluoride to produce acid fluorides (e.g., see paragraph bridging pages 4332-4333 showing activation via cyanuric fluoride; see also scheme 1 wherein HATU + DIEA is disclosed).

For ***claim 31 and 36***, Carpino et al. disclose ethanolamine, which is used as a scavenger (e.g., see page 4329, column 1, paragraph 1; see also Solomons and Lide, page 94, Table 1 showing anion).

For ***claim 41***, Carpino et al. disclose one or more cycles wherein in step (b) both quenching and deprotection occur and the subsequent step (c) comprises sequential neutral extractions (e.g., see page 4320, Scheme 1, Bsmoc-AA_2-AA_1-OR → H-AA_2-AA_1-OR step; see also experimental; see also page 4327, column 2, middle paragraph, "It has now been found that the process can be simplified by switching to Bsmoc chemistry since the byproduct adduct 15 formed in this case is soluble in water, thus avoiding the need for extraction with an acidic buffer. This results in fewer complications with emulsions and loss of growing peptide into the aqueous phase.).

For ***claim 42***, Carpino et al. disclose the use of sodium chloride (e.g., see abstract, "Application to the latter methodology represents a significant improvement over the corresponding Fmoc-based method for rapid solution synthesis due to the opportunity to use water or saturated sodium chloride solution rather than an acidic phosphate buffer to remove all byproducts").

For ***claim 44***, Carpino et al. disclose the use of ethyl acetate (e.g., see generally experimental section; see also page 4332, Methods 2 and 3 see also Table I, Bsmoc-Leu-

OH entry). In addition, the Examiner notes, "the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA1955). Here, the choice of solvent would be routine.

For ***claims 45 and 46***, Carpino et al. disclose, for example, room temperature, which falls within 0 to 50°C (e.g., see Experimental).

For ***claim 49***, Carpino et al. disclose, for example, the use of TFA to acidolytically remove the permanent protecting groups (e.g., see Scheme 1, last step).

For ***claim 55***, Carpino et al. also disclose a separate deprotection step followed by one or more aqueous extractions (e.g., see Scheme 2 wherein each of the amino acids represent a "separate" deprotection step when reacted with $N(CH_2CH_2NH_2)_3$ followed by aqueous extractions; see also Table 2 wherein Boc, T-Bu etc represent separate deprotections; see also Experimental section).

Response

6. Applicant's arguments directed to the above 35 U.S.C. § 102 rejection were fully considered (and are incorporated in their entirety herein by reference) but were not deemed persuasive for the following reasons. Please note that the above rejection may been modified from it original version to more clearly address applicants' newly amended and/or added claims and/or arguments.

[1] Applicants argue, "In essence, one skilled in the art utilizing the described extraction conditions of Carpino, even after performing hundreds of extractions would not be able to

effectively remove the deprotonated, quenched compound, e.g., to a level below 1%" (e.g., see 5/29/07 Response, pages 6-8, especially page 8, paragraph 1).

[1] Applicants' arguments are not commensurate in scope with the claims. First, Applicants' claims encompass a method that uses "hundreds of extractions." That is, claim 28 does not read wherein the method is performed such that the extraction step is not repeated more than a certain number of times. Furthermore, it is unclear how "hundreds of extractions" to a level below 1% was even calculated. Applicants state that 10^{-7}% dissociation would occur at neutral pH but again it is unclear how this value was obtained. As noted previously, the arguments of counsel cannot take the place of evidence in the record. *In re Schulz*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). Moreover, ethanolamine would still function as a scavenger even if, *assuming arguendo*, it did exists at this alleged 10^{-7} % (e.g., see 1/26/07 Non-final Office action, arguments 3-4, wherein this point was addressed at length).

[2] Applicants argue, "As calculated by the Examiner, at a pH of 12 ethanolamine would be deprotonated to an extent of approx 11%. Consequently after one extraction step under mildly basic conditions it is removed from the reaction mixture in small amounts. Complete removal of H-AA_2-NH-CH_2CH_2-OH in anionic form ... under mildly basic conditions can only be achieved performing a multitude of mildly basic extractions. Applicant has calculated that 40 extraction steps are required to reduce the amount of quenched compound in the reaction mixture to a level below 1%. This implies a very inefficient, laborious and lengthy process ... Accordingly, it may be concluded therefore that ethanolamine utilized at mildly basic conditions i.e., that is below pH 12, cannot be regarded as a scavenger containing an anion-forming moiety

within the scope of the present invention" (e.g., see 5/29/07 Response, paragraph bridging pages 9 and 10).

[2] The Examiner respectfully disagrees. Even if, *assuming arguendo*, all of Applicants' aforementioned facts were considered to be true, the conclusion that ethanolamine could not be considered to be a scavenger within the meaning of the claims still would not follow. To the contrary, Applicants' broad claims would necessitate a finding that ethanolamine is indeed a scavenger because no meaningful limitations are placed on it. For example, the claims do not read, "the scavenger is used to remove residual activated carboxylic functions to a level below 1%" as erroneously purported. To the contrary, the claims allow for "any" amount of removal no matter how small. Furthermore, the claims do not preclude the use of 40, 100, etc. extractionsThe claims merely read that "one or more aqueous extractions" may be performed (e.g., see claim 28, step (c)). In addition, no limitation is placed on the "efficiency" of the peptide synthesis (e.g., 99% yield, with 99% purity is not recited). Thus, "less efficient" scavengers like ethanolamine fall comfortably within the scope of Applicants' broad claims.

Accordingly, the 35 U.S.C. § 102 rejection cited above is hereby maintained.

Claim Rejections - 35 USC § 103

7. Claims 28-31, 36, 41, 42, 44-46, 48, 49 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carpino et al. (Carpino, et al. "The 1,1-Doxobenzo[b]thiophene-2-ylmethyloxycarbonyl (Bsmoc) Amino-Protecting Group J. Org. Chem. 1999, 64, 4324-4338) (10/23/03 IDS Reference AR) and Tolle et al. (WO 00/71569) (Published November 30, 2000)

and Houghten et al. (Houghten, R.A.; Pinilla, C.; Blondelle, S.E.; Appel, J.R.; Dooley, C.T.; Cuervo, J.H. "Generation and use of synthetic peptide combinatorial libraries for basic research and drug discovery" *Nature* 1991, *354*, 84-86).

For ***claims 28, 30, 31, 36, 41, 42, 44-46, 49 and 55***, Carpino et al. teach all the limitations stated in the 35 U.S.C. 102(b) rejection above (incorporated in its entirety herein by reference), which anticipates and, as a result, renders obvious claims 28, 30, 31, 36, 41, 42, 44-46, 49 and 55.

The prior art teaching of Carpino et al. differ from the claimed invention as follows:

For ***claim 29***, the prior art teachings of Carpino et al. differ from the claimed invention by not specifically reciting the amounts of reagents as carboxylic component, coupling additive greater than coupling reagent greater than amino component. Carpino et al. only show carboxylic component greater than amino component.

For ***claim 48***, Carpino et al. fail to teach the use of automation.

However, the combined references of Tolle et al. and Houghten et al. teach the following limitations that are deficient in Carpino et al.:

For ***claim 29***, the combined teachings of Tolle et al. and Houghten et al. teach the use of coupling reagents used in conjunction with coupling additives (e.g., see Tolle et al., page 11, line 3 wherein activated N-hydroxysuccinimide esters are used; see also Houghten et al., Tables and figure). In addition, differences in concentration (e.g., carboxylic component, coupling additive greater than coupling reagent greater than amino component) will not support the patentability of subject matter encompassed by

the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235Carpino(CCPA 1955). Here, it would be conventional and within the skill of the art to *identify the optimal concentration*. It is well-established that merely selecting proportions and ranges is not patentable absent a showing of criticality. In re Becket, 33 U.S.P.Q. 33 (C.C.P.A. 1937). In re Russell, 439 F. 2d 1228, 169 U.S.P.Q. 426 (C.C.P.A. 1971).

For ***claim 48***, the combined teachings of Tolle et al. and Houghten et al. disclose the use of automation (e.g., see Tolle et al. figure 2).

It would have been obvious to one skilled in the art at the time the invention was made to use the scavenging resins for the combinatorial synthesis of proteins as taught by the combined teachings of Tolle et al. and Houghten et al. with the Bsmoc Amino protecting groups as taught by Carpino et al. because Carpino et al. state that their method can be used with scavenging resins and that it is also applied to combinatorial synthesis i.e., the references represent analogous art. Furthermore, one of ordinary skill in the art would have been motivated to use the scavenging resins as taught by Tolle et al. because Tolle et al. explicitly state that their resins will "minimize the requirement for isolation of intermediates" that are produced in peptide synthesis using scavengers (see Carpino et al., Field of the invention), which would encompass the peptide synthesis disclosed by Carpino et al. In addition, Houghten et al. teach that their "split and mix" method can be advantageously used to produce large peptide libraries (e.g., see Houghten

et al., abstract), which would encompass the peptide libraries of Carpino et al. Finally, one of ordinary skill in the art would have reasonably expected to be successful because all three references teach the successful synthesis of peptides and both Carpino et al. and Tolle et al. teach successful examples of using amine scavengers in peptide synthesis.

Response

8. Applicant's arguments directed to the above 35 U.S.C. § 103(a) rejection were fully considered (and are incorporated in their entirety herein by reference) but were not deemed persuasive for the following reasons. Please note that the above rejection has been modified from it original version to more clearly address applicants' newly amended and/or added claims and/or arguments.

[1] Applicants argue, "The argument proffered above to address the § 102 rejection apply equally well to this rejection" (e.g., see 5/29/07 Response, page 10).

[1] To the extent that Applicants are merely repeating their previous arguments, the Examiner contends that those arguments were adequately addressed in the above sections, which are incorporated in their entireties herein by reference. Thus, Tolle et al. and/or Houghten et al. are not required to remedy these alleged deficiencies.

Accordingly, the 35 U.S.C. § 103(a) rejection cited above is hereby maintained.

Double Patenting

9. Claims 28-39, 41, 42, 44-46, 48, 49, 55-57 and 63 are provisionally rejected under the

judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 28-51 of copending Application No. 10/692,354 (2004/0082760 A1) (referred to herein as '354). An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1986). Although the conflicting claims are not identical, they are not patentably distinct from each other because, for example, claims 28-39, 41, 42, 44-46, 48, 49 and 51-55 are generic to all that is recited in claims 28-51 of '354 or represent overlapping scope.

For ***claim 28***, the '354 application claims the same method steps (a)-(c) and also the same method step (b)' and thus is identical to the claimed method with the exception of the optional step (d) recited in the '354 application.

For ***claims 29-39, 44-46, 48, 49, 51, 52, and 63***, the '354 application claims the exact same method steps (e.g., see '354 application, claims 29-39, 41-44, 46-48, 50 and 51).

For ***claims 41 and 42***, 'the '354 application claims that both quenching and deprotection can occur (e.g., see '354 application, claim 28). In addition, the "basic" extractions disclosed in claim 41 of '354 anticipate claim 41 of the present invention. Furthermore, it would have been obvious to one having ordinary skill in the art to modify embodiments of '354 that fall outside the scope of the present application (e.g., the acidic extractions) to select a specifically disclosed embodiment that falls within the scope of the present application (e.g., the basic or neutral

extractions) because these embodiments describe similar method steps (e.g., extraction) with similar results (e.g., purification). One having ordinary skill in the art would have been motivated to do this because these embodiments (e.g., neutral and basic extractions) are disclosed as being preferred embodiments in the '354 application and the dependent claims of '354 teach toward Applicants' claimed invention (e.g., see claims 42 and 43 of the '354 application).

For ***claim 55***, the '354 application also claims a separate deprotection step (d), followed by one or more aqueous extractions (e.g., see '354 application, claim 28, step (d)).

For ***claims 56 and 57***, the '354 application claims Applicants' preferred benzyl β-alaninate (e.g., see '354 application, claim 39), which contains a carboxylate anion.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response

10. Applicant's arguments directed to the above double patenting rejection were fully considered but were not deemed persuasive for the following reasons. Please note that the above rejection has been modified from it original version to more clearly address applicants' newly amended and/or added claims and/or arguments.

[1] Applicants argue, "In response, Applicants will address the obviousness-type double patenting rejection upon indication that claim 28 is deemed to be allowable except for the obviousness-type double patenting rejection." (e.g., see 5/29/07 Response, page 11).

[1] The rejection will not be held in abeyance (e.g., see MPEP § 804 B. Between Copending Applications—Provisional Rejections, "The 'provisional' double patenting rejection ***should continue to be made by the examiner*** in each application as long as there are conflicting claims in more than one application unless that "provisional" double patenting rejection is the only rejection remaining in one of the applications."). Here, a double patenting rejection is NOT the only rejection remaining in one of the applications and thus the double patenting rejection is proper.

Accordingly, the double patenting rejections cited above are hereby maintained.

Conclusion

Applicant's amendment necessitated any new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D Epperson whose telephone number is (571) 272-0808. The examiner can normally be reached Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Jon D. Epperson/
Primary Examiner, AU 1639